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TITLE: Intervention to Decrease Risk for Sexually Transmitted Diseases (STDs) and the Associated Negative Reproductive Health Outcomes in Women Aboard Ships: A Biopsychosocial Approach

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13. ABSTRACT (Maximum 200 Words) Unintended pregnancies (UIPs) and STDs with their sequelae of ectopic pregnancy continue to be epidemic among active duty enlisted women. Such reproductive health problems result in major morbidity among affected women as well as posing a potential threat to combat readiness. UIPs and STDs result from complex interactions between biological and behavioral factors in military women. The ultimate control in preventing such morbidities must rely on both behavioral and biologic strategies. The primary aim of the project is to develop, implement, and evaluate an intervention which emphasizes correct information, motivation and behavioral skills building (IMB Model) coupled with non-invasive screening using urine-based amplified DNA techniques to detect C. trachomatis and N. gonorrhoeae and urine based pregnancy testing. A pre-test, post-test experimental design was employed to evaluate the impact of the behavioral intervention on the experimental group using both self-report questionnaires (UIP/STD psychosocial and behavioral risk factors) and results from the STD and pregnancy screening tests as measures. The control intervention will consist of a prevention program focusing on nutrition, breast cancer, fitness and injury prevention. Questionnaires and urine testing will be done at pre-test, mid-study, and post-test 6-12 months later. Subjects will include junior enlisted Marine women with N=1000 in the experimental group and N=1000 in the control group.			
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3. INTRODUCTION

Overall Goal: To prevent sexually transmitted diseases (STDs) and unplanned pregnancies (Focus curriculum) and to promote good nutritional habits and reduce sports/training injuries (Fitness-for-Life curriculum) through the provision of information, communication and problem-solving skills training, use of program-specific videos, and group discussions which emphasize prevention of risk behaviors and negative peer influences. The curricula for both components are implemented in 4, two-hour sessions that occur during Recruit Training (Parris Island, SC). Screening for pregnancy and prevalent STDs, including chlamydia, gonorrhea, and trichomonas is also included.

Participants: Junior, enlisted women Marine Recruits who voluntarily agreed to participate in the program were randomly assigned by platoons to either the Focus (Study condition) or Fitness-for-Life (Control condition) Curricula at arrival at recruit training.

Assessments: All participants complete a self-report questionnaire of their knowledge, attitudes, beliefs, and behaviors regarding STDs, unplanned pregnancies, nutrition and fitness at T-1 baseline (prior to participation in the Program at Recruit Training Regimen-RTR, Parris Island, SC), at T-2 after completing Marine Combat Training (MCT at Camp LeJeune, NC, approximately 5 weeks from graduation from recruit training) which was preceded by boot leave, and at T-3 which is 9-11 months post-MCT at their first duty assignment or MOS School. These individuals are also screened for pregnancy and STDs at each of the three assessment periods (See Appendix 4 for Study Timeline).

Program Evaluation: The primary goal of the program evaluation is to determine the feasibility and effectiveness of the Focus curriculum for preventing unplanned pregnancies and STDs and the Fitness-for-Life curriculum for promoting good nutritional habits and reducing sports/performance injuries in junior enlisted women Marines.

Specific Aims:

- (A) Develop, implement, and evaluate a reproductive health educational and cognitive-behavioral skills-building intervention (behavioral intervention) designed to modify knowledge, psychosocial and behavioral risk factors associated with UIPs and STD acquisition.
- (B) Test the relevance of the Information, Motivation, and Behavioral Skills (IMB) Model in explaining the determinants of behaviors linked with UIPs and STDs.
- (C) Define the prevalence of UIPs and STDs, emphasizing the most common bacterial agents, such as C.trachomatis and N.gonorrhoeae, and their sequelae of PID and ectopic pregnancy.
- (D) Utilize pregnancy and STD diagnostic screening tests as biological markers to validate self-reported behaviors and to evaluate the impact of the behavioral intervention.
- (E) Assess the performance of non-invasive, non-culture-base screening tests for the detection of as C.trachomatis and N.gonorrhoeae by ligase chain reaction (LCR) technique on first void urine compared to standard tests applied to (invasive) endocervical and urethral specimens by the presence or absence of urogenital symptoms.

4. BODY

Overview

The research methods, results, and discussion are described below in relation to the Statement of Work for the grant period August 7, 1999-August 6, 2000. Overall plans for the extension for Year 5 of the project included the following tasks: a) completion of the recruitment of all women Marines to participate in the project and the completion of the actual implementation of the intervention during the recruit training period (curriculum for FOCUS/FITNESS FOR LIFE); b) completion of the baseline clinical/biological and self-reported questionnaire assessments for the initial intervention phase of the project (T-1); c) hiring and training of all additional staff needed to implement the data collection for the initial follow-up period at MCT (T-2); d) completion of 60% of the follow-up assessments (clinical/biological and questionnaire assessments) of participants at T 2; e) hiring and training of the additional staff needed to implement the assessments for the final assessment period (T 3) at the participants' first duty station; f) begin the actual T-3 assessments at the 3 geographic sites (clinical/biological and questionnaire assessments); and g) initiation of the baseline clinical/biological data including early descriptive data analyses.

STATEMENT OF WORK (SOW)

The following summarizes progress on the SOW activities:

- (A) Select a group of surface destroyer and submarine tender ships to focus initial data collection of which two ships will be targeted as study ships for the current study.
 - (a) The target population for implementation of the project is US Marine Corps Recruits from the Marine Corps Recruiting Depot (MCRD), Recruit Training Regimen (RTR) on Parris Island, SC. To date, we have approached 2,282 women Marine recruits to participate in the *FOCUS-Fitness for Life* intervention. Of these women 95% voluntarily consented to participate in the program (N=2,160). Of these women, 1,059 (49%) were assigned to the *FOCUS* program and 1,101 (51%) were assigned to the *Fitness for Life* program. Currently, 1,592 (74%) have completed either program, were screened for STDs (chlamydia, gonorrhea, trichomonas, and bacterial vaginosis), and completed a self-reported questionnaire to assess baseline knowledge, attitudes, beliefs, and behaviors related their reproductive health; 355(16%) recruits are still in Recruit Training and are expected to graduate while 213(10%) have been discharged from Recruit Training.
 - (b) To date, 1,471 (92%) of the participants who have graduated from Recruit Training have been followed at Marine Combat Training (MCT) at Camp LeJeune, NC, an add-on training program for women Marines. At this initial follow-up, the participants were screened for pregnancy and STDs (chlamydia, gonorrhea, trichomonas), and completed

(c) A brief self-reported behavioral assessment.

(d) A second follow up of the participants is just underway (begun July 1, 2000). We have established follow-up sites on Okinawa, Japan (Camp Hansen, Camp Lester and others), in Jacksonville NC (Camp LeJeune, Camp Geiger, and others), and southern California (Camp Pendleton, 29 Palms, San Diego) to reach the women Marine participants who are assigned to duty stations in and around these regions. The women are screened for pregnancy, STDs (chlamydia, gonorrhea, trichomonas), and complete a self-reported behavioral assessment. In addition to these locations, MCRD at Parris Island, SC will serve as the coordinating site to reach women who are stationed in other regions of the country and abroad. These women will only complete a second-follow-up questionnaire. This phase of the study was launched in July 2000 and has resulted in 86 follow-ups to date (59 women have been screened for STDs and pregnancy and completed a questionnaire and 27 have completed a questionnaire only).

(e) While establishing the originally planned second follow-up phase of program 6 months post MCT graduation, we soon realized that many of the women Marines were not on post at their assigned first duty station. Many of the women were still completing their Marine Occupation Specialty (MOS) School or were on deployment, which is contrary to our preliminary research and earlier briefs with the Marine School of Infantry staff. During our start-up phase of the second follow-up, it became apparent that we would not be able to reach the majority of the women until after month 9 post MCT graduation. This three month delay has forced us to extend the lag period between the two follow-up phases of the study (9-11 months), and thus, requiring a longer timeframe for completion of the project. (This change in the study design requires us to request funding for the Investigators and data analytic staff to June 30, 2002. This extended timeline, however, will increase the likelihood that we will be able to effectively evaluate the experimental intervention).

(a) Brief the Commanding Officers (COs) of the target populations.

(a) To date, all COs at the participating sites have been briefed. In order to establish sites to conduct the second follow-up of the study, the following briefs were conducted in the last year (see Appendix 1 for a sample copy of the brief packet):

Jacksonville, NC: Mr. George Reynolds, Chief of STD Control and Mr. Donald Neil, STD/HIV Disease Intervention Specialist for the Naval Hospital at Camp LeJeune provided access to all Branch Medical Clinics and Battalion Aide Stations (BAS) for all bases in the Jacksonville, NC area. The initial brief was conducted in March 1999.

Southern California: CMDR Sainten, USN, MC, CO for all Branch Medical Clinics and BAS on Camp Pendleton was briefed in April 2000. A similar brief has taken place with LCDR Cruz and LT Sonders, USN, MC at 29 Palms, the points of contact at 29 Palms.

Okinawa, Japan: CAPT Schall, USN, MC, Directorate of Branch Clinics was briefed to gain access to all Branch Medical Clinics and BAS on the bases on Okinawa, Japan where women Marines are stationed (June 2000).

(b) Conduct elicitation research (focus groups) in order to develop a self-report question to assess knowledge, attitudes, and beliefs, and behaviors of the target population and to develop a military-specific behavioral intervention to reduce risk or UIPs and STDs in the target population, including development, implementation, and evaluation of the intervention.

(a) All program materials, including videos, training exercises, training materials, and evaluation (assessment) instruments have been developed.

(b) All study participants have been enrolled into the *FOCUS-Fitness for Life* intervention program as described above in section A-a. All but 16% of the participants have successfully completed the program. These remaining participants are still in their 13-week Recruit Training period and are scheduled to complete the program by September 15, 2000.

(c) The proposed timeline for completion of the MCT follow-up phase of the study is January 2001 (to capture those women who are on medical graduation hold). To date, 1,471 women have completed the first follow-up as described above in section A-b.

(d) The second follow-up of the women Marine participants at their first duty station was initiated in July 2000 and is scheduled to be completed by November 2001 as described above in sections A-c and A-d above.

(c) Review STD logs and clinical records to establish the prevalence of productive health outcomes in the target population.

(a) All activities related to this task were completed prior to this fiscal year.

(b) We determined the baseline prevalence for C.trachomatis, N.gonorrhoeae, and T.vaginalis in the target population (See Appendix 3, text of the poster of baseline STD screening results presented at the Chlamydia 2000 international meeting in Helsinki, Finland August, 2000). We found an overall 13% rate of STD infections among entering Marine recruits including 11.6% infected with chlamydia, 2.2%

with gonorrhea and 1.6% with trichomonas.

(d) Test the feasibility of non-invasive STD screening tests (urine) for chlamydia and gonorrhea in comparison to standard invasive tests.

(a) All activities related to this task were completed prior to this fiscal year.

(e) We also determined the performance profiles for the 3 different collection methods to detect C.trachomatis and N.gonorrhoeae by nucleic acid amplification tests applied to endocervical, first catch urine, and self-administered vaginal swab specimens.(See Appendix 3).

(f) Test the acceptability of screening for pregnancy in the target population.

(a) All activities related to this task were completed prior to this fiscal year.

(g) We also determined that the best method for collection was a combination of endocervical and vaginal swab collections. In addition we were able to determine that self-administered vaginal swab collection is feasible and an efficacious method among this population.

5. KEY RESEARCH ACCOMPLISHMENTS TO DATE

- Designed and successfully implemented an intense 8 hour training program within a complex recruit training schedule to decrease STDs and IUPs
- Determined the feasibility of follow-up of individual participants over 3 different time periods during their first enlistment
- Described basic reproductive health behaviors including sexual activity, sexual partner information, contraceptive use, among others
- Determined the prevalence rates for common STDs among Marine women recruits: C.trachomatis (11.6%); N.gonorrhoeae (2.2%), and T.vaginalis (1.6%)
- Evaluated the performance profiles of 3 different techniques for collecting STD specimens (endocervical, first part urine and self-administered vaginal swabs) and determined that vaginal or a combination of endocervical and vaginal detect the most infections.
- Determined that self-administered vaginal swabs are acceptable to these young women

6. REPORTABLE OUTCOMES

- (A) Developed and produced a complete manual describing "how to" implement the FOCUS/FITNESS FOR LIFE interventions
- (B) Produced a skills building teaching video, "GOOD TO GO" as a part of this project which is used in the intervention training
- (C) Developed a computerized and manual system for tracking recruits throughout their first enlistment
- (D) Presented a poster at the international Chlamydia 2000 meeting in Finland in August 2000 describing our STD screening results to date including assessment of performance of 3 different specimen collection techniques (see Appendix 3).

7. CONCLUSIONS TO DATE:

- (A) Implementation of an intense cognitive-behavioral intervention to decrease acquisition of STDs and unplanned pregnancy is possible within a military setting.
- (B) Implementation of a universal STD and pregnancy screening program is possible within a military setting over time.
- (C) Asymptomatic and undetected STDs especially C.trachomatis are common among young women Marines.
- (D) Young women Marines are placing themselves at risk for acquisition of STDs and unplanned pregnancy by engaging in risky sexual behaviors including having unprotected sexual intercourse, having sexual intercourse with multiple partners, among other risky behaviors.
- (E) It is critical to develop an annual universal STD screening program for STDs to be implemented immediately among young military women.
- (F) Early findings of high rates of STDs and risky behaviors linked to STD acquisition and IUPs dictate that the implementation of an STD/IUP prevention program for young women Marines is essential to support combat readiness.

PROPOSED PROJECT ACTIVITIES: JANUARY 1, 2001-JUNE 30, 2002

Description of the Proposed Extension of Contract Activities To Be Completed:

(A) Complete a second follow-up (T-3) on all of the participating women Marines.

- (a) All participants will be followed at their first duty station. Based on preliminary tracking assessments, we anticipate that we will be able to locate 100% study participants who are still enlisted in the Marine Corps. We estimate that 60% of the women will be in our three primary targeted sites (Jacksonville, NC, Southern CA, Okinawa, Japan). These women are contacted by the Site Coordinators (Brenda Zepeda, Japan, Richelle Balazs, NC, and Tyrese Trabelsi, CA) via telephone and scheduled for a follow-up clinic appointment to screen them for STDs, pregnancy, and to complete a self-report questionnaire (see Appendix 2 for a copy of the extensive protocol manual which describes these activities in detail).
- (b) Participants who are stationed at commands other than our three primary target sites, are contacted via a letter and are asked to complete a self-reported questionnaire. An attempt to also have them mail in a self-administered vaginal swab for chlamydial and gonococcal testing is also planned.

This follow-up phase of the study will be completed by November 2001 (see sections A-c- and A-d, pages 1-2 above).

(B) Evaluate the efficacy of the experimental (*FOCUS*) and control (*Fitness for Life*) intervention programs to prevent STDs and unplanned pregnancies.

Baseline Data (T-1)

- (a) To date, all data related to the baseline STDs (chlamydia, gonorrhea, trichomonas, bacterial vaginosis), Well-Women's clinic visits records (e.g., cytopathology, STD-related symptoms), and self-reported questionnaires (e.g., knowledge, attitudes, beliefs and behavior related to reproductive health) have been collected. Most of these data have been entered into the computer, statistically cleaned for consistency, and are concurrently undergoing preliminary, descriptive data analyses. A projected timeline for completion of all the clinical and biological data analysis is December 31, 2000 (see Appendix 3 for a copy of the poster presentation to IV European Chlamydia Congress-Chlamydia' 2000 meeting in Helsinki Finland for a description of these data to date).
- (b) The statistical cleaning of the questionnaire data is just underway. Upon completion of these activities knowledge, psychosocial, and behavioral scales using Cronbach's Alphas will be completed by December 31, 2000. Descriptive statistics will be completed by February 2001 and final multivariate statistical models that describe the study participants at baseline will be completed by April

2001. Given the large volume of these data, multiple, scientific, peer-reviewed journal articles, paper presentations, and reports to the Department of the Army will be written and disseminated concurrently.

Initial Follow-up Data (T-2)

- (c) Collection of the initial follow-up data from MCT graduates is 76% complete. It is anticipated that collection of these data will be 100% completed by January 2001 as originally planned. Data entry of the data already collected has begun and will be completed by February 2001. Data cleaning and descriptive statistics will be completed by May 2001. Logistic regression statistical models that evaluate the 'short-term' efficacy of the *FOCUS-Fitness for Life* intervention program will be completed by June 2001. Scientific, peer-reviewed journal articles and paper presentations will be written concurrently which describes these interim data. Progress reports to the Department of the US Army will be written and disseminated concurrently.

Second Follow-up Data (T-3)

- (d) The second follow-up data collection is just underway. Due to the need to increase the lag period between the initial and second follow-up, this task is anticipated to be completed by November 2001 (as described above). The data entry and statistical cleaning will be ongoing and will be completed by January 2002. Descriptive data analyses will also be ongoing and will be completed in February 2002. Evaluation of the 'long-term' efficacy of the *FOCUS-Fitness for Life* intervention program will require complex statistical comparisons of the baseline and second follow-up data, comparisons between intervention and control groups, and clustering effects by original platoons. These analyses will be completed by April 2002. Scientific, peer-reviewed journal articles, paper presentations, and progress reports to the US Department of the Army will be written and disseminated by June 30, 2002 (see Appendix 4 for schematic overview of the project activities covered during the proposed funding period).
- (e) We anticipate that we will have an overall 15% attrition from our original sample of 2,160 women by the second follow-up (n= 1,836). Most of the women who will not be followed will have been discharged from the Marine Corps (12%) and some will have declined further participation in the study (3%). Of the women we will follow, we estimate that we will reach 40% or 734 for follow-up in non-primary target areas; these women will complete a questionnaire only. Additionally, we estimate that we will reach 60% or 1,102 women in our 3 primary target locations for follow-up STD and pregnancy screening and questionnaire. Of all the women we will follow, we estimate that we will reach 450 participants (200 with questionnaire only and 250 with questionnaire and pregnancy and STD screening) by December 30, 2000 under the current funding

period. Therefore, we will need to follow the remaining 1,386 participants (534 completing a questionnaire only and 852 with questionnaire and pregnancy and STD screening) during the proposed extension period.

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APPENDICES

Appendix 1. FOCUS BRIEF

Appendix 2. T-3 Protocol Manual

Appendix 3. Comparison of 3 specimen collection techniques-endocervical, first catch urine and self-administered vaginal swab to screen for *C.trachomatis* (ct) and *N.gonorrhoeae* (gc) by NAATS in Women Marine recruits

Appendix 4. Timeline of Project Activities

Appendix 1.

FOCUS BRIEF

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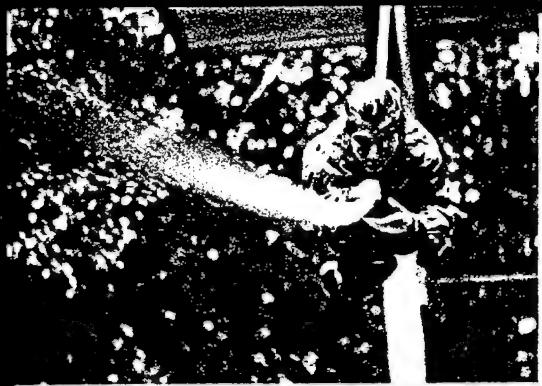
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PROGRAM OBJECTIVE

To prevent unplanned pregnancies and sexually transmitted diseases in junior, enlisted women Marines.



Until now, the Marine Corps has taught only two methods of contraception...

“FOCUS” CURRICULUM GOALS

- Educate participants about the risk and impact of unplanned pregnancies, STDs and HIV.
- Provide participants with factual information about effective methods of contraception and STD outcomes.
- Familiarize participants with the basics of a GYN exam and the female reproductive anatomy.

“FOCUS” CURRICULUM GOALS

- Develop participants' communication and decision-making skills regarding sexual behaviors and use of contraception.
- Provide participants with information about the effects of alcohol use.



ROLE-PLAY EXERCISE: “LET’S TALK ABOUT SEX AND CONTRACEPTION”

Imagine that you are in the beginning weeks of a new relationship. You really like this guy a lot and think this relationship has the potential to develop into something special. But you want it to be different than previous relationships. You've promised yourself that in any new relationship you will start off by being open and honest in talking about sex before you're in the heat of the moment. You also realize that beginning the conversation is difficult and a little scary. What do you say?

PROGRAM OVERVIEW

Recruit Training
Baseline

MCT
Initial Follow - up

First Duty Station
Second Follow-up

Recruitment
Questionnaire
STD/Pregnancy Screen
Programs
“FOCUS”
“Fitness for Life”

Questionnaire
STD/Pregnancy Screen

Questionnaire
STD/Pregnancy Screen

RESEARCH TEAM

Parris Island

Project Coordinator/Health Educator
Project Assistant
Health Educators (4)
Health Educator/Clinical Coordinator
Laboratory Technician
System Tracking Analyst

Camp LeJeune

Site Coordinator/Data Collection
Project Assistant
Laboratory Assistant

Okinawa, Japan

Site Coordinator

San Francisco

Project Assistant
Biostatistician
Data Specialist
Statistician
Data Manager
Data Entry Team

Southern California

Site Coordinator

Approached → 1799

Enrolled → 1709 (95%)

Program Completion → 1079 (63%)



Ongoing Program
Participation → 630 (37%)

Initial Follow-Up → 912 (85%)

Second Follow-Up → 0

DEMOGRAPHIC CHARACTERISTICS

(N = 1109)

Age (mean)	18.7
Race/Ethnicity	
African American	16%
Asian/Pacific Islander	4%
Caucasian	54%
Latino	22%
Other	4%
Marital Status	
Single	95%



SEXUAL RISK FACTORS

(n = 873)

Sexually Experienced	85%
History of Pregnancy	13%
History of STDs	8%

SEXUAL BEHAVIORS (3 MONTHS)

Sexual Activity	85%
Sexual Partners	
1	60%
2-5	24%
>6	<1%
Hormonal Contraception (usually)	42%
Condom Use (usually)	39%

STD SCREENING

STD-related symptoms	25%
STD diagnosis	16%
Chlamydia	11%
Gonorrhea	3%
Trichomonas	2%

After years of fitting in,
maybe it's time to stand out.



Appendix 2.

T-3 Protocol Manual

Overview of the FOCUS Program

Collaborators: Drs. Cherrie Boyer, PhD, Mary-Ann Shafer, MD, and Julius Schachter, PhD, University of California, San Francisco and LT Heidi Kraft, PhD, CDR Richard Shaffer, PhD and CAPT (ret) Stephanie Brodine, MD, Naval Health Research Center, San Diego, CA.

Overall Goal: To prevent sexually transmitted diseases (STDs) and unplanned pregnancies (Focus curriculum) and to promote good nutritional habits and reduce sports/training injuries (Fitness-for-Life curriculum) through the provision of information, communication and problem-solving skills training, use of program-specific videos, and group discussions which emphasize prevention of risk behaviors and negative peer influences. The curricula for both components are implemented in 4, two-hour sessions that occur during Recruit Training (Parris Island, SC). Screening for pregnancy and prevalent STDs, including chlamydia, gonorrhea, and trichomonas is also included. Positive pregnancy and STD results are conveyed to participants, and referral for care is provided.

Participants: Junior, enlisted women Marine Recruits who voluntarily agreed to participate in the program were randomly assigned by platoons to either the Focus or Fitness-for-Life Curricula.

Assessments: All participants complete a self-report questionnaire of their knowledge, attitudes, beliefs, and behaviors regarding STDs, unplanned pregnancies, nutrition and fitness at baseline (prior to participation in the Program at RTR, Parris Island, SC), after completing Marine Combat Training (MCT at Camp LeJeune, NC) which was preceded by boot leave, and 6-9 months post-MCT at their first duty assignment or MOS School. These individuals are also screened for pregnancy and STDs at each of the three assessment periods.

Methods: For follow-up of participants at their first duty station or MOS School, the FOCUS on-site research assistant will contact participants by phone and remind them of the program and schedule a clinic appointment to complete a self-report questionnaire and to be screened for STDs and pregnancy. The on-site FOCUS research assistant will assume responsibility for administering all questionnaires, and collecting and processing all biological specimens.

Program Evaluation: the primary goal of the program evaluation is to determine the feasibility and effectiveness of the Focus curriculum for preventing unplanned pregnancies and STDs and the Fitness-for-Life curriculum for promoting good nutritional habits and reducing sports/performance injuries in junior enlisted women Marines.

June 20, 2000

Laboratory Screening Tests for the FOCUS Program

Overview: Women Marines who have consented to participate in the FOCUS Program fill out a self-administered health questionnaire and are screened for STDs and pregnancy at three different times during the study: (1) at recruit training at Parris Island, SC; (2) at the end of MCT at Camp LeJeune, NC; and (3) approximately 6 months after MCT at their first duty station or MOS School. The questionnaire and laboratory tests help us to evaluate how successful the FOCUS Program was at preventing STDs and unintended pregnancy over time among the women who participated in the program.

Contacting Women Marine FOCUS Program Participants for Follow-up: Women Marine participants will be contacted by telephone from the FOCUS Program research office. The letter will give them and time, date, and clinical site (e.g., assigned branch medical clinic) to attend to be screened for STDs and pregnancy and to complete a follow-up questionnaire. The Program coordinator will be available at the assigned clinic site to assist the woman Marine to complete the laboratory collection and administer the questionnaire. All appointments will be carefully coordinated with the appropriate staff at the designated clinic site beforehand.

Laboratory Tests Performed: FOCUS Program participants submit a first part urine specimen (first 20-30 cc of urination) for testing for chlamydia and gonorrhea, and pregnancy. In addition, they provide a self-administered vaginal swab. Self-administered vaginal swabs have been recently shown to be an excellent technique for obtaining accurate chlamydia, gonorrhea, and trichomonas samples. Chlamydia and gonorrhea are tested using the new and very sensitive nucleic acid amplification tests (NAATs) at a research laboratory in San Francisco by the Program Investigators; the tests used are the ligase chain reaction tests (LCR by Abbott Laboratories). Trichomonas is placed in culture media and read at 2 and 5 days on site by the research assistant. All laboratory tests associated with the FOCUS Program are handled by the Program's on-site coordinator.

When a Laboratory Test is Positive: The exact protocol for contacting a FOCUS program participant who has a positive test may vary somewhat according to the local (branch) clinic schedules and clinical protocols. In general, the FOCUS Program nurse coordinator will contact the designated medical officer about the positive test result. For positive STD tests, the medical officer will follow (branch) clinic protocol for STD follow-up for treatment and for contact tracing. For positive pregnancy tests, the medical officer will also follow (branch) clinic protocol for medical confirmation and follow-up.

When a Clinician or Designated Clinic Staff Has A question about the FOCUS Program or Laboratory Tests: The clinician or designated clinic staff person can contact the research nurse coordinator or Program Investigators, Dr. Shafer or Dr. Boyer:

Program Nurse Coordinator:

Ms. Kim Flinn Work: 843-228-3853; Home: 843-522-9829 mermaid1doc@islc.net

Principal Investigators:

Cherrie Boyer, PhD Office: 415-502-4689; Beeper: 415-719-8327 boyer@itsa.ucsf.edu
Mary-Ann Shafer, MD Office: 415-502-4689; Beeper: 415-719-9824 shafer@itsa.ucsf.edu

June 20, 2000

T-3 Protocol: Introduction

Required Personnel and Set-Up at Each Study Site Prior to Start of Follow-up

1. Follow-up sites (Camp LeJeune and vicinity, Southern California bases, Okinawa, Japan bases) were pre-determined as the most likely places women Marines are assigned as their first duty station.
2. Each study site area will have a Project Site Coordinator to contact the women participants, make individual or small group appointments to meet at local BAS/clinics for survey administration and for clinical specimen collections.
3. The site coordinator will give participants instruction on completion of the survey, assist the women Marines in specimen collection, perform the initial processing of lab tests, storage and will package and ship clinical specimens to the San Francisco laboratory of the Researchers.
4. There will be a designated point of contact person within the Navy medical community at each study site for the Project.
5. There will be a site-specific protocol developed for each site outlining the methods to contact individual women about the T-3 follow-up, how to make the women's appointments for the follow-up assessment, how to administer the survey and obtain the clinical specimens from the women, and how to store and send the clinical laboratory tests to the University of California, San Francisco laboratory.
6. There will be specific space in an appropriate BAS/clinic at each site that will serve as the place where the participating women will complete the survey and provide clinical specimens under the supervision of the site coordinator.
7. There will be appropriate freezer space (-70 °C) to store specimens prior to shipment to the San Francisco laboratory, and appropriate incubator space (37 °C) for the 5 day *T. vaginalis* incubation. There will be an identified microscope which the identified person (site coordinator/identified PMT, laboratory technician) will be able to read the *T. vaginalis* cultures.

T-3 Tracking and Data Entry Protocol

1. Monthly, each T-3 collection site will receive a telephone contact and on-site lab collection roster and labels for clinical specimens for Marines in their area who are in the T-3 collection window (6-9 months post MCT graduation). See attached rosters. These rosters are based on MCT graduation date and MCC location.
2. To create the most up-to-date telephone and on-site lab rosters, Parris Island will update the Parris Island tracking system with the following data fields from the Marine Corps database as close to roster output as possible:

VERF MCC	Current MCC
VERF RUC	Current RUC
T-3 PLATOON	Current platoon
MCC CITY	Current MCC location
T-3PHONE	Current work phone number
RANK	Current rank
FUTRUC	Future RUC
EDA	Estimated date of arrival that their future duty station

3. Discharged marines will be noted in the Parris Island tracking system and students will be closely monitored so that collections can be made within the T-3 collection window.
4. On-site coordinators will be responsible for contacting the Marines to schedule their survey and screening sessions. When ever possible the phone rosters will have a primary and secondary work telephone number for each Marine. The first telephone number will be from the Marine Corps database and the second number will be from the Marine Corps e-mail system.
5. Calls should be made during normal military working hours. Trying to avoid morning physical training sessions, lunch breaks and other mandatory training times (i.e. most Thursday afternoons). On-site coordinators should use the local base locator and/or DCAC office for missing, incorrect or difficult to reach Marines.
6. A telephone contacts log should be maintained for each telephone call. See attached log design.
7. At the end of the month, on-site coordinators will fax their monthly on-site lab collection roster and copies from their telephone contacts log to Parris Island for final accounting and review of outstanding collections.

8. Marines who have not completed a T-3 assessment and who are still within the collection window will be added to the next month's rosters.
9. After 7 attempts to reach a Marine, she will be considered lost to study.
10. As rosters arrive on Parris Island, the following data entry fields will be completed:

T-3 COLLECTION DTE	T-3 Collection date
T-3 COMMENTS	Comments from T-3 collection
T-3 SEP DATE	Discharge date if discharged prior to T-3 collection

11. All completed T-3 surveys should be sent to Dr. Boyer at UCSF.
12. Parris Island will continue to follow the clinical tracking and quality control standard operating procedures used for both T1 and T2: includes contact and confirmation of treatment for all positive test results, maintenance of the clinical tracking database and compilation of all final lab rosters.

Contact and Phone Script: First Contact with Participating Women:

You only have 5 minutes to complete the introduction and make a follow-up appointment by telephone as you will be, in most instances, contacting these women at their work units

1. Rosters of women to target for T-3 follow-up by date and duty station site will be generated by the primary research team at Parris Island under the supervision of Kelli Betsinger, Project Director, based at Parris Island, SC. These lists will be generated monthly, will include identifying contact information and will be forwarded to each site coordinator.
2. Each site coordinator will confirm the location of the targeted women using the base or Marine-wide locator system as needed.
3. Each participant will be initially contacted by the site coordinator by phone to re-introduce the Program and the protocol for the T-3 survey and clinical specimen collection.

NOTE:

The following script is to be used at the first telephone contact with the women participants, most of whom are at their first duty stations. All women on the rosters participated in the Focus-Fitness for Life intervention, have completed surveys and provided clinical specimens during recruit training. Most participants completed surveys and provided clinical specimens a second time at the end of MCT. The current component of the Program is a second follow-up of all the participating women. It will also include administration of a survey that is similar to the other two she has already completed and the same clinical sample collection as was accomplished at MCT. All women to be contacted have already provided written consent for these activities as a part of the initial introduction of the Program at Parris Island. The follow-up consists of administration of the T-3 follow-up survey and collection of clinical specimens at a designated BAS/clinic site (vaginal swabs and a first-part urine sample).

The Telephone Contact Script

1. *Introduce yourself*
2. We are contacting you once again to request your continued participation in the FOCUS-Fitness for Life Program that you participated in at recruit training and again at MCT. As you may recall from recruit training and MCT, this special Program was developed to help women Marines to take care of themselves. To refresh your memory, while in recruit training, you participated in 5 sessions which taught you about women's health issues. Some of you learned about unplanned pregnancy and STDs and how to prevent them while others learned about physical fitness and nutrition.
3. At the start of the Program while in Recruit Training you filled out a survey, provided a urine sample and vaginal swabs to test for STDs and pregnancy. Then again at the end of MCT, you completed the survey and the clinical specimen collections. At that time we told you that we would be contacting you at your first duty station for this part of the Program.
4. This current component of the Program will consist of you completing another survey and providing clinical samples as you have done before. As you may recall, these tests will tell you whether you are pregnant or have been infected with an STD, even if no symptoms are present. I will be calling you to make an appointment to meet me at a near-by BAS or clinic in the near future. When you arrive, I will have you collect the clinical specimens in private and will have you complete another survey. As before, all of this is handled in a confidential manner. It is important that you do not urinate for 2 hours before you get to the clinic to make your urine specimen is a good one for the lab tests.
 - Do you have any questions?
 - I'd like to contact you before your appointment. Is this the best telephone number to contact you? If not, what is the best number? (record new number in your log)
 - Also, to mail out your appointment slip, I will need to make sure I have your correct address. Recite the address slowly. Is this correct? If not, what is the correct address?
 - If you are on your period, you can still come in for the tests. If you prefer, we can make the appointment when you are not expecting your period. When was you last period? When do you expect your next period? (write date in your log)

- It is important not to douche the day before or the day of your appointment with me.
- *Complete your conversation with:* I want to thank you ahead of time for participating in this very important and unique health Program for women Marines.
- I look forward to seeing you on (recite date) at (recite time), (recite clinic name and room number).
- I will send you a clinic appointment card to attend the clinic if you need to show your supervisor and information about transportation to the clinic. The entire process will take about 30-40 minutes, but I will make your appointment for one hour, to give you ample time to complete the survey and collect the specimens.
- If you need to cancel or change the appointment for any reason, you can call me at (recite your telephone number) and leave me a message and I will call you back.

Setting up the Appointment for the BAS Clinic

1. Each site coordinator will work with a designated Navy Medical point of contact at the appropriate BAS/clinics to set up follow-up appointments and send out appointment cards to the women participants.
2. Each site coordinator will work with the appropriate clinic staff to identify the best time and space to hold the follow-up appointments, administer the survey, obtain and process and store the clinical specimens.
3. Each site coordinator will work with an appropriate medical/laboratory/PMT person regarding small space needs to collect, process, and store the clinical specimens prior to shipment and to read/verify *T.vaginalis* cultures.

Reminder Telephone Call for Scheduled BAS/Clinic Follow-up Visit

1. Call scheduled participants the working *day before* the scheduled appointment to remind them of the time and place of the appointment.
2. Problem solve with them if they are having trouble of any sort in making it to the appointment.
 - Make sure they received the appointment slip in the mail so they may be excused from duty to come to the clinic.
 - Review with them their transportation plan to get to the clinic.
3. Ask them if they have any questions.
4. Remind them that you will be personally greeting them at the visit.

The T-3 Clinic Visit

1. Greet the woman as she enters and show her to your room.
2. Explain to her about the specimen collection and the survey as outlined below.

The Urine Specimen

- If you are on your period today, you can still do the tests.
- First, I will give you a urine cup and a plastic tube with 3 swabs in it. The cup and plastic tube have your name on it. The urine specimen cup is marked with a dark line. That line is the amount of urine we would like you to put in the cup (this is only about 1 tablespoon). Your urine specimen will be tested for STDs-chlamydia and gonorrhea and for pregnancy. We will also be checking for another STD called Trichomonas.
- You will be able to get the result of the pregnancy test before you leave today.
- However, the STD test results take longer. This is because the project is a research project and these tests are evaluated in San Francisco, California. We will not be able to give you results 4 weeks. So, if you think that you may have an STD, do not wait for us to notify you. See a health care provider as soon as possible. If I can assist you in speaking to the appropriate person to make an appointment, please let me know.

Hold up the cup with yellow colored food coloring to demonstrate how much urine we need.

- You will then go to the head.
- Once you are in the head, be sure to urinate in the cup **first** before you continue to urinate in the toilet. This is very important so that we can provide you with the best test results. **We only need the first tablespoon of urine to be put in the cup!** Remember it is also important that you do not go over the dark line. If you do go over the line, **do not pour off any the extra urine.** This will help us give you accurate test results. Wipe yourself well.
- Make sure the top is screwed tightly on the cup. Put the cup on the floor and begin your vaginal swab collections.

The Vaginal Swabs

- If you are using a tampon, take it out before inserting the swabs.
- Even if you are on your menstrual cycle today, you can do the swab test. Any questions?
- Take the three swabs out of the plastic tube.
- Take one swab out of the plastic tube and insert it approximately 1 inch into the vagina.
- Rotate it **three times** around the vaginal mucosa (the soft moist skin inside the vaginal opening) and then withdraw the swab and place it back into the plastic tube-place cotton tip to the bottom of tube.
- Take the second swab and insert it into the vagina, approximately 1 inch. Place it back into the plastic tube.
- Repeat this procedure for the third swab.
- As soon as you are finished screw the top tightly onto the tube, then place the tube back in the plastic specimen bag.
- Seal the bag and bring your samples back to me.

Note:

- *When the Marine returns with her specimens, note the number of volume of urine in cc's in the cup on the roster. Make sure that she has done the swabs and returned them to you at this time also.*
- *Take one of the unmarked cotton swab from the transport tube and place it in the top part of the trich pouch.*
- *Do the pregnancy test while the woman is present. If it is positive, she needs to be referred to clinic for follow-up of a confirmatory test. (see script below)*
- *Tell the woman that a medical officer will be contacting her if any of the STD tests are positive in a few weeks to a month, and will be referred to the appropriate medical clinic for care and treatment.*
- *As soon as she has left, go immediately to the lab. If the lab is in another place, it is necessary to put the specimens on ice in a ice chest for transportation except for Trichomonas (keep at room temperature until reach incubation).*
- *Once in lab, store the urine in the refrigerator and start processing the swabs first, especially the Trichomonas In Pouch TV see Lab directions.*
- *Then "squish" swab tip around in upper chamber of pouch's liquid. Then seal top of chamber. Move upper chamber liquid into lower chamber Place in incubator.*

The Survey

- You will fill out a survey about your health and activities since graduating from Recruit Training. Like before, all your answers are confidential. We will not use your name on any of the data. This information will be kept with the researchers, Drs. Boyer and Shafer in San Francisco. No one else will have access to this information, so it is important for you to be as honest as you can when you answer each question to help us figure out better ways to keep women Marines healthy. If you feel you can not answer a question in an honest manner, it is best to skip that question. Incorrect information will give us the wrong impression about women Marines' health.
- The survey should take about 20 minutes. If you have any questions while filling out the survey, just ask me and I will help you. When you are finished, place your survey in the folder and give it to me.

Pregnancy Test Results

- Give each woman her pregnancy test result at the end of the clinic visit.

If the Urine Pregnancy Test is Positive:

- Our test result indicates that your urine pregnancy test is positive. That is, you are currently pregnant.
- However, I strongly recommend that you go to the BAS/clinic at (give name of nearest clinic) to confirm the results.

If the Urine Pregnancy Test is Negative:

- Our test result indicates that your urine pregnancy test is negative. That is, you are currently not pregnant.
- However, if you feel that you may be pregnant, I strongly recommend that you go to (give name of nearest BAS/clinic) to be re-tested.

T-3 Prep/Supplies

Supplies for each subject:

- questionnaire & pencil
- urine collection cup
- 1 cotton swab: (plastic shaft!)
- 2 dacron swabs (mark black/blue on top)
- 1 capped 15 cc plastic culture tubes (swabs)

In clinical laboratory for each subject:

- 1 small plastic LCR tube-CT/GC (brown top)
- freezer tubes for urine transport
- 5 cc plastic disposable pipettes
- 12 ID labels for lab specimens/Marine
- 1-urine cup; 1-blue top tube; (small 5 cc)
- 1-trich pouch; 3 extra labels;
- pregnancy test kits
- Trich In-pouch
- latex gloves, pencils (#2) to mark slides

Preparations Needed 1 Week Prior, 1 Day Prior, and on Collection Day

1 Week Prior to Collection Day

- Check and make sure you have roster of women to contact and their ID labels sent from Kelli Betsinger at PI
- Call and introduce project to participating women; have appointments mailed out (to be done by you or clinic directly).
- Pre-label one culture tube, LCR tube and Trich In-Pouch for each participant.
- Mark black line at the 20 cc level on the urine cups with permanent marker.
- Place the 2 cotton and 1 dacron tipped swabs into the labeled culture tube and close screw top. Mark dacron tip tube with 2 blue/black permanent marker.

1 Day Prior to Collection Day

- Call and remind woman/women about appointment the next day.
- Call BAS/clinic and remind your point of contact that you will be there and at what time.

Collection Day

- Prior to woman's arrival to appointment, organize and lay out all lab materials, labeled tubes, etc out in the laboratory for easy processing later at the BAS clinic.
- For the collection you will need the following materials:
 - a) Name (s), locale, telephone contact number of participant(s)
 - b) Number of set(s) of participant labels needed
 - c) Number of swab instruction sheets needed
 - d) One (1) roll of tape
 - e) One (1) Instruction script
 - f) Extra pencils
 - g) Participant supplies: each Marine receives one of each of the following:
 1. Survey
 2. Pencil
 3. Urine collection cup labeled at distribution with Marine's name
 4. Pre-labeled swab tube containing 2 cotton and 1 dacron swab

Directions For Patient Collection Of Urine, and Vaginal Specimens

Urine and vaginal swab specimen collection (for Chlamydia/Gonorrhea LCR, pregnancy test)

Each Marine will provide a first part "dirty urine" (the first 20 cc's of urine stream) into a pre-labeled collection cup pre-marked at the 20 cc level.

- Set up a space in or near your designated room in the BAS/clinic site. On a tray, for each woman, place a urine cup (pre-marked with a thick, dark marking pen at the 20 cc level) and the labeled culture tube with vaginal swabs.
- Give a short brief to the Marine(s) prior to the specimen collection. It is probably better to collect the specimens before the questionnaire is administered as it is likely the woman will want to urinate as soon as she gets there! (Use the **T-3 Brief: Introduction, Urine Specimen and Vaginal Swab Collection Brief Sheets**).
- Marine(s) will be given the urine cup and the vaginal swab tube and be shown the head. As you hand them their urine cup, remind them again that only a tablespoon of the first part of their urination is needed as marked on the container. Remind them to not pour out any of the urine if they exceed the requested tablespoon or 20 cc's.
- Remind them to **wipe themselves well with toilet paper before collecting the vaginal swabs**.
- Instruct the Marine(s) to proceed to head to fill urine cups and to collect the 3 vaginal swabs.
- Tell them to return the samples to you in your room when they are done.
- **Deliver urines to the lab as soon as possible within a 60-minute timeframe.** If this is not possible, put urines on ice until they can be refrigerated.
- When the woman returns, have her take the appropriate swab and place it in the top chamber of the trich pouch herself with you holding it upright and open. Then you close the top. You can move the liquid into the lower chamber when she has left. (Keep swabs for Trichomonas vaginalis warm and process in the lab as soon as possible-must be within 20 minutes maximum!-the sooner the better!!!).

Lab Processing

Timeline for testing of specimens collected from Marines Processing

Immediate post-collection

- Refrigerate urine specimen 4 C → (refrigerators are 40°C)
- Transfer 2 cc urine to transport tube; freeze at -70°C
- Perform pregnancy test with remainder of unfrozen urine (room temperature for pregnancy test)
- Inoculate CT/GC swab into LCR tube; refrigerate until can freeze
- Freeze -70°C within 48 hrs of collection.
- Make BV slide and air-dry overnight.
- Organize slides in boxes for mailing. Put confidentiality (subject) # in pencil on frosted portion prior to use. Collect slides until have 50 and then can ship in Slide tray (has room for 50 slides).
- Inoculate upper chamber of TV; then move liquid from upper to lower chamber and incubate @ 37°C. Read at 48 hour (2 days); if negative then reincubate @ 37°C and reread at 5 days.
- OK - make duplicate urine freezer tube - keep stored -70°C.

Immediately after Specimen Collection-Processing :

Lab Technician/Research Assistant Instructions:

I. Self-administered Vaginal Swabs

Vaginal Swabs: *The vaginal swabs should be processed **immediately** after they are received from the Marines and transported to the clinical lab.*

Swab # 1: cotton swab: T. vaginalis (Trichomonas In-Pouch)

- Make sure the In-Pouch is pre-labeled with Marine's name.
- Before starting, if there is no fluid in the upper chamber, fill the upper chamber halfway with fluid via the canal that connects the upper and lower chambers.
- Tear open the pouch at the notch just above the closure and using the pull-tabs, pull the pouch open enough to admit the swab. Unmarked swab-cotton.
- Insert the swab into the upper chamber and massage the swab with your fingers on the outside of the pouch; (as mentioned earlier, can have Marine insert swab herself directly into upper pouch when she returns from head to you with specimens).
- Massage liquid in upper chamber to the lower chamber gently using the plastic view frame provided by manufacturer being careful not to break bag.
- Close the pouch by rolling the top down several times and folding the close tabs back.
- Re-incubate pouches @ 37°C vertically in a 35 mm plastic slide tray so that the writing on the label is right side up.

****Remember: marked tube - marked swab.*

Swab # 2: color-marked DACRON swab: Chlamydia/Gonorrhea (LCR)

- Place the swab with the blue marking on the end (this is the dacron swab) into the pre-labeled brown-topped LCR tube.
- Break the stick firmly (stick with kit is scored for this). Make sure the sticks are broken at the same line in order to fit well in the LCR tube. Secure brown cap onto tube (**if they are not on correctly they often leak and will lose specimen during transport!**). Make certain the tubes have Marine's name label on each tube.
- Place LCR tubes upright into the transport tubes. Refrigerate immediately overnight and transport to the hospital in the morning.
- At the Naval Hospital or clinic laboratory, freeze and store at -70°C until can overnight mail to SF.
- Transport in the SAF-T-PAK using dry ice by FED EX **overnight** delivery to Dr. Schachter's laboratory.

II. Urine Specimens for LCR and Pregnancy Testing

- Take urine specimens out of the refrigerator in small batches to process.
- ***Before pipetting sample, MIX urine in cup very well!!!***

Transfer to freezer tubes for freezing and shipping

- Transfer about 2 cc's of mixed urine using 5 cc plastic disposable pipettes into the small plastic capped tubes for the urine transport.
- Refrigerate urine freezer transport tubes immediately at Branch Medical research lab.
- On the day after specimen collection, transport these tubes to the LeJeune Naval Hospital Laboratory and freeze at -70°C (must be **within 3 days**).
- Frozen urine specimens are to be transported to Dr. Schachter's laboratory in San Francisco using the SAF-T-PAK transport container via FED EX **overnight** delivery. The San Francisco laboratory will mail the container back to you after they have received the specimens.

When the urine transfer to freezer tubes is complete and tubes have been refrigerator, the pregnancy testing can begin.

Pregnancy Testing

- Process the urine pregnancy tests as directed by the package insert in the Abbot Laboratories pregnancy test kits. Perform this while the woman is still there so she can have the immediate result. Use timers and be meticulous.
- If there are any questions, consult with _____ at the Naval Hospital or Dr. Shafer, UCSF by phone or email.
- All positive pregnancy tests must be repeated using another test kit.
- All positive pregnancy tests must also be confirmed by Navy Medical when the woman Marine is referred there with a "positive" pregnancy test.

5 DAY FOLLOW-UP LABORATORY PROCESSING FOR TRICHOMONAS VAGINALIS (TV) SPECIMENS

5 Days from day of collection, if thurs pm collection, read tues pm or wed am:

- Read the pouches for presence of TV at 5 days. Do not go over this time as the Trichomonas begin to die and you may miss a positive. Follow the directions for inserting the chamber into the plastic frame and read at 10X in the clinical microscope. If you collect specimens on collect specimens on Thursday night, read the specimens on Wednesday. Can read @ 48 hours also; if neg-repeat @ 5 days)
- For further description, see details in Trich In-Pouch directions provided by manufacturer and directions below.

PROCEDURE FOR READING TRICH IN-POUCH AT 5-DAYS

Study research laboratory person on our project at MCT will be trained to read TV at the women's gyn clinic at the hospital. All positives must be verified by the designated medical officer or licensed and approved laboratory technician for your site before being a confirmed positive Trich. The pouches must be read at 5 days. After that, the Trichomonas may die off and become negative.

- Trichomonas must be read at 5 days.
- Rub the bottom of the lower chamber along the edge of a table or counter in order to dislodge the trichomonads from the bottom of the chamber, where they colonize.
- Place upper chamber of pouch into microscope clip for microscope viewing.
- Observe pouches under microscope at 4x and 10x using microscope clip.
- If no motile trichomonads are seen at 5 days, the specimen is negative.

How to interpret In-Pouch results:

- **Positive:** If motile trichomonads are seen at any time in the pouch, test is positive.
- **Negative:** If no motile trichomonads are seen after a total of 5 days measured from the time of the initial inoculation, the test is considered negative; discard the In-pouch.
- **All positive tests must be officially reviewed and read by the designated Medical Navy officer or designated approved lab technician within 24 hours of finding a positive.**

STORAGE AND TRANSPORT INSTRUCTIONS:

- Store both urine and LCR tubes in refrigerator until they can be frozen.
- **LCR vaginal and urine specimens must be frozen within 72 hours of collection.** Once specimens are frozen they may be kept indefinitely before being analyzed by the lab (*that is only if held at -70°C*).
- Place test tubes with urine into SAF-T-PAK carrier with dry ice for shipping.
- Place LCR tubes into SAF-T-PAK carrier with dry ice for shipping.
- BV slides (labeled with confidentiality number) are to be placed together in plastic shipping boxes.
- Fill out one requisition form per patient. Write specimen collection date, and adhere one of the labels with Marine's name and medical record number. Write the study number in bold letters.
- Note "FCU" and Vaginal swab at the bottom of the requisition.
- Place a copy of the roster of participants' samples being shipped to Schachter's lab in the shipping container.

On Day Following Collection:

- Pack specimens in the Saf-T-Pak transport tubes, place in a cooler with ice and transport immediately to the freezer at the Naval Hospital laboratory.
- Report all positive tests (the only results available at this point) to Dr. Shafer (leave on voice mail 415-476-4384 and fax to office : 415-476-6106, Attention Anthony Kung); also, report all positive tests (pregnancy, Trichomonas) to Kim Flinn or Kelli Betsinger at the Well Women's Clinic at PI TEL: 843-228-4116/4117; or by email (see contact sheets)
- Label the questionnaires and stamp each page with the participant's confidentiality number. Review each questionnaire for questionable or inconsistent data. Flag any problems with a post-it note with a brief description of the problem.
- Fax the roster of participants marked with urine cc's and pregnancy test results to Kim Flinn.

Weekly or Monthly as Numbers of Subjects Dicate a shipment:

(See Storage and Transport Instructions)

- Ship surveys to Dr. Cherrie Boyer by 2 day FEDEX (Priority mail from Okinawa, Japan once a month).

5-Days after Collection:

- Make final read of the Trichomonas In-Pouch.
- Report all positive tests to Kim Flinn and Kelli Betsinger as above.

If you have any questions about the collection of specimen, contact Dr. Shafer directly . If you have any questions about laboratory transport of specimens contact Jeanne Moncada in Dr. Schachter's laboratory.

T-3 COLLECTION ROSTER

UCSF/CA LAB
POSTER

MAY T-3

T-3 LAB ROSTER

MAY T-3

CLINICAL FOLLOW-UP: TRACKING FOR T-3

1. Site coordinator informs Parris Island Clinical Tracking coordinator, Ms. Kim Flinn by email, fax or phone of positive tests for pregnancy and Trichomonas.
2. Ms. Flinn verifies with site coordinator on receipt of information.
3. Ms. Flinn receives positive lab data from UCSF laboratory on lab raw roster data forms from Ms. Jeanne Moncada by fax/mail.
4. Ms. Flinn confirms female's location using established locator protocol.
5. Ms. Flinn contacts SMO (senior medical officer) at the medical facility where female will be treated, and forwards positive results
6. Ms. Flinn follows-up with email of information to SRO.
7. Log into clinical tracking book by Ms. Flinn at PI:
 - Name of female with positive test
 - Date received info from UCSF/T-3 site, date labs collected
 - SRO: date of contact, name of medical contact
 - Date, follow up treatment
 - SSN
 - Platoon
 - School
 - + Lab data
 - GC urine/swab
 - CT urine/swab
 - Trichomonas
 - Pregnancy

Note: Positive pregnancy labs at T-3

- Pregnancy tests are run on the day of collection. Pregnancy tests that are positive are forwarded to CDR Schall by email for Okinawa follow-up. (Same procedures that are in place for MCT should be followed for all other sites.)

SURVEY III LETTER

Ms. Kelli Betsinger

Project Director

FOCUS-Fitness for Life Program

Contact Telephone with answering machine

Date: _____

Dear _____:

We are contacting you to request your participation in the next phase of the FOCUS-Fitness Fitness for Life Program. As you may recall from Recruit Training and MCT the goal of this special project developed by the University of California and the Naval Health Research Center in California to help women Marines to take care of themselves. To refresh your memory, while in Recruit Training you participated in five sessions which taught you about women's health issues. Some of you learned about unplanned pregnancy and STDs and how to prevent them while others learned about physical fitness and nutrition.

At the start of the program while in Recruit Training, you filled out a survey, provided a urine sample and vaginal swabs to test for STDs and pregnancy. You repeated the survey and the clinical specimen collections at the end of MCT. At that time we told you that we would be contacting you at your first duty station for this part of the program.

We are now contacting you to request that you complete the enclosed survey. Your participation in this part of the program is very important. Information on the survey will assist us in determining if our program was helpful to young women Marines and give us ideas about developing better health programs for young women Marines in the future. Every woman Marine in our study has an important and unique role to play to help us make health care better for yourselves and future women Marines. That is why your completion of the survey and returning it to us is so important.

As we have done in the past, we will make sure that all your responses are held in the strictest of confidence. Only our program staff will see your survey. Your name or any other personal identification information will not be used. Information from all participants is grouped together to make general statements about program participants. Please complete the survey by answering all of questions as honestly as you can. This is important because untruthful responses or missing information makes it difficult for us to draw accurate conclusions about our participants. It is OK to use either a pen or pencil, but make sure your responses are clearly marked. After completing the survey please place it in the enclosed self-addressed, postage paid, envelope and put in any US postal mailbox.

If you have any questions about this survey or any part of the program, you can contact one of the FOCUS staff at (843) 228-2806 or email us at betsingerka@mcrdpi.usmc.mil. We sincerely thank you for your participation in this program. It has been a pleasure working with you. We wish you well in all of your future endeavors.

Sincerely,

Kelli Betsinger, BA

Cherrie Boyer, PhD

Mary-Ann Shafer, MD

CONTACT LIST OF T-3 STAFF AND INVESTIGATIONS

UCSF Investigators and Staff

Cherrie Boyer, Ph.D.

Principal Investigator

University of California, San Francisco

Mary-Ann Shafer, M.D.

Co-Principal Investigator

University of California, San Francisco

Anthony Kung

Administrator

University of California, San Francisco

NHRC Investigators

CMDR Richard Shaffer

NHRC

CAPT (ret) Stephanie Brodine

Graduate School of Public Health

San Diego State University

LT Heidi Kraft

NHRC

Parris Island, SC Research Staff

Kelli Betsinger

Project Director

Kim Flinn

Research Assistant, Project Nurse

MCRD

Jill Bowen

Administrator

MCRD

Camp LeJeune Research Staff

Richelle Balazs
Research Assistant

MST SGT Curtis Brookshire

Donald Neil
Disease Intervention Specialist HIV/STD
Naval Hospital

GE Reynolds
Chief, STD Control
Naval Hospital

Camp Pendleton Staff

Tyrese Trabelsi
Coordinator

LT. Murillo
13 Area Clinic Department Head

HMC Ferreira
13 Area Chief

Liz England
Front Desk Clerk

Okinawa Research Staff
Brenda Zepeda
Research Assistant

Appendix 3.

**Comparison of 3 specimen collection techniques-endocervical,
first catch urine and self-administered vaginal swab to screen
for *C.trachomatis* (ct) and *N.gonorrhoeae* (gc) by NAATS in
Women Marine recruits**

**COMPARISON OF 3 SPECIMEN
COLLECTION TECHNIQUES-
ENDOCERVICAL, FIRST CATCH URINE
AND SELF-ADMINISTERED VAGINAL
SWAB TO SCREEN FOR *C. TRACHOMATIS*
(CT) AND *N. GONORRHOEAE* (GC) BY
NAATS IN WOMEN MARINE RECRUITS.**

MA Shafer¹, C Boyer¹, F Pang,² J Moncada²,
A Dubovtsev¹, S Brodine³, R Shaffer³, J Schachter²
University of California, San Francisco,
Departments of Pediatrics¹ and Laboratory
Medicine²; Naval Health Research Center,
San Diego, CA³.

INTRODUCTION

Unprotected sexual intercourse results in major medical and social morbidities of STDs and unintended pregnancies (UIPs) that can uniquely threaten the combat readiness of military women. Reported chlamydial infection rates in this population range from 5-9% or more. Little data is available on the rates and relationships among STDs and health behaviors in this group.

This study represents the baseline clinical data of women Marine Corps recruits participating in an 8-hour, cognitive-behavioral, skills-building intervention (*FOCUS-FITNESS FOR LIFE*) to prevent STDs and UIPs.

Objectives

1. To determine the performance of 3 specimen collection methods to detect *C. trachomatis* and *N. gonorrhoeae* by nucleic acid amplification test applied to endocervical, first catch urine, and self-administered vaginal swab specimens.
2. To describe the prevalence of *C. trachomatis*, *N. gonorrhoeae* and *T. vaginalis* and to define the relationship between STDs detected at baseline, behavioral, and sociodemographic factors in this national sample of young women.

METHODS

Subjects: Young women entering 13 weeks of recruit training at the U.S. Marine Corps Recruiting Depot in Parris Island, SC were enrolled in the *FOCUS-FITNESS FOR LIFE* intervention. This study represents the first 1661 women who voluntarily consented to participate (6% declined).

Clinical Procedures: These recruits undergo a routine pelvic exam with STD and Pap smear screening within 2 weeks of arrival. The study questionnaire and specimen collection (cervical, FCU and 3 self-administered vaginal swab specimens) were incorporated into this exam.

1. **Survey:** A self-reported survey querying about behaviors, clinical history regarding STDs, pregnancy, and other risk factors were administered upon written, informed consent.
2. **Specimens:** Cervical, vaginal and FCU samples for *C.trachomatis* (CT) & *N.gonorrhoeae* (GC) were processed using LCx™ (Abbott). A vaginal swab was used for *T.vaginalis* (TV) using In-Pouch TV™ (Biomed). Cervical specimens were processed by military licensed labs; FCU and vaginal samples for CT/GC were processed in the lab of an author (JS); and TV was incubated @37° C and read at 2 and 5 days.

RESULTS

CONCLUSIONS

1. STDs (13%) are prevalent among young women entering the Marine Corps.
2. Only 40% used condoms at last sex.
3. Vaginal and endocervical swabs combined yielded the best sensitivity rates for CT & GC.
4. Vaginal swabs are the best single technique of the 3 possible techniques for CT & GC.
5. The performance of LcxTM to detect GC was poor with self-administered vaginal samples performing the best of 3 sites (72% sensitivity).

IMPLICATIONS

1. Young women entering Marine Corps recruit training represent a diverse ethnic/racial and geographical national sample for study of reproductive health issues.
2. Epidemic STD rates among these young women dictate the need for screening.
3. Prevention of risky sexual behaviors is urgently needed in this group.
4. A combination of endocervical and a spiral sampling of the vaginal wall may offer the best single technique for obtaining CT and GC samples during a pelvic exam.
5. Self-administered vaginal samples are the best single technique for detecting CT and GC in this young population of women.

Table 1 Sociodemographics of Sexually Active Women Marine Recruits (N=1414)

Age (median = 18 years; range 17-33 yrs)

17 years	8%
18 years	46%
19 years	21%
20-33 years	25%

Race/Ethnicity

White	57%
Hispanic	19%
African American	15%
Other	9%

Marital Status

Never married	90%
Married	8%
Separated/divorced	2%

Table 2 Sexual Activity

Sexual Activity

Ever N=1408/1646 (86%)

Sexual debut (median 16 yrs, range 6-25 yrs)

< 12 years	1%
12-15 years	35%
16-17 years	45%
>18-19 years	19%

Years sex active (median 3 yrs, range 1-16 yrs)

< 1 year	26%
2 years	22%
3 years	18%
4 years	13%
> 5 years	21%

Table 3 Pregnancy, STD, Partner Hx

Pregnancy ever 16%

STD ever (“Told by MD”) 10%

Partners in lifetime

1 partner ever 18%

2-4 partners 39%

≥5 partners 43%

Last 3 months

Did not have sex 13%

1 partner 61%

> 1 partner 26%

≥ 1 Casual partner 25%

**Table 4 Contraceptive Use at Last
Sexual Intercourse (%)**

No method only	19
Withdrawal only	12
OCPs (pills) only	13
Depo-Provera/Norplant only	5
Condoms only	40
Other only (spermicide only)	3
OCPs & condoms	6
Depo-Provera/Norplant & condoms	2

* 15% (211/1414) did not have sex in past 3 mos

Table 5 Prevalences of STDs

<u>Any STD</u>	13.0%
<u><i>C. trachomatis</i> (any “+” by Lcx^R)</u>	
Endocervix, urine, vagina*	11.6%
<u><i>N. gonorrhoeae</i> (any “+” by Lcx^R)</u>	
Endocervix, urine, vagina	2.2%
<u><i>T. vaginalis</i> (“+” by Trich In Pouch^R)</u>	
Vaginal swab	1.6%

* Self administered vaginal swabs

Table 6 Prevalences of STDs by Type of Specimen: Chlamydia*

C. trachomatis

Any positive	11.6%
Endocervix	7.5%
Urine	8.5%
Vagina*	10.0%

Sensitivity** for *C. trachomatis* by specimen

Endocervix	65%
Urine	73%
Vaginal*	83%
Endocervix <u>and</u> urine	86%
Endocervix <u>and</u> vagina*	91%
Vagina* <u>and</u> urine	95%

* Self-administered vaginal swab

** Positive result by any method

Table 7 Prevalences of STDs by Type of Specimen: *N.gonorrhoeae*

N.gonorrhoeae

Any positive	2.2%
Endocervix	1.1%
Urine	0.5%
Vagina*	1.7%

Sensitivity for *N.gonorrhoeae* by specimen

Endocervix	45%
Urine	24%
Vagina*	72%
Endocervix <u>and</u> urine	52%
Endocervix <u>and</u> vagina	100%
Vagina* and urine	76%

*Self-administered vaginal swab

Official Abstract Form

COMPARISON OF 3 SPECIMEN COLLECTION TECHNIQUES- ENDOCERVICAL, FIRST CATCH URINE AND SELF-ADMINISTERED VAGINAL SWAB TO SCREEN FOR *C. TRACHOMATIS* (CT) AND *N. GONORRHOEAE* (GC) BY NAATS IN WOMEN MARINE RECRUITS. MA Shafer¹, C Boyer¹, F Pang², J Moncada², A Dubovtsev¹, S Brodine³, R Shaffer³, J Schachter²

University of California, San Francisco, Departments of Pediatrics¹ and Laboratory Medicine²; Naval Health Research Center, San Diego, CA³.

Objective: To determine the performance profile of 3 specimen collection methods to detect CT and GC by NAATs applied to endocervical (Cx), first catch urine (FCU) and self-administered vaginal swab (Vag) specimens in women Marine recruits.

Methods: At entry into the military, all women Marine recruits are screened for cervical CT and GC using LCx^R (Abbott) and have Pap smears taken during routine pelvic exams which are processed by a military contract laboratory. To date, 1110 women have voluntarily consented to participate in a behavioral intervention to prevent STD acquisition and unintended pregnancy; 6% refused participation. All participants completed a self-report survey and provided a FCU and 3 self-administered vaginal swabs for screening for CT and GC using LCx^R (Abbott). An additional vaginal swab was obtained for *T. vaginalis* (TV) culture (*Trich In- Pouch*^R).

Results: Analyses were based on 796 sexually experienced women who had all 3 specimens tested. Ss had a mean age of 18.8 years, were ethnically diverse (55% W, 21% H, 17% Af Am, 7% As/Other), and largely never-married (92%). 13% reported a history of pregnancy and 8% reported a history of an STD(s). In the past 3 months, 15% reported sexual activity, and 25% had \geq 2 partners. Currently, 40% used hormonal birth control, 76% used condoms, and 25% complained of genital symptoms on clinical history.

127(16%) of infections were identified:
90(11%) CT, 21(3%) GC, 16 (2%) TV.

Table: Sensitivities for CT and GC by Collection Method (N=796)		
<i>C. trachomatis</i>		
<u>Cx</u> 68%	<u>FCU</u> 72%	<u>Vag</u> 88%
<u>Cx+FCU</u> 86%	<u>Vag+FCU</u> 94%	<u>Cx+Vag</u> 97%
<i>N. gonorrhoeae</i>		
<u>Cx</u> 43%	<u>FCU</u> 32%	<u>Vag</u> 81%
<u>Cx+FCU</u> 52%	<u>Vag+FCU</u> 86%	<u>Cx+Vag</u> 100%

Conclusion: STDs are common among young women Marine recruits. Vaginal swabs proved to be the best single method for identifying CT and GC. Urine performed poorly in identifying CT and GC. Combining 2 collection methods improved the sensitivities with the Cx+Vag combination yielding the best results for identifying CT and GC. Consequently, when screening during a pelvic exam, it appears that the simultaneous sampling of the cervix and vagina, e.g., one swab at endocervix followed by a "spiral" sampling technique of the vagina on exiting, would likely identify the most CT and GC infections without increasing clinician time or costs.

Appendix 4.

Timeline of Project Activities

Timeline of Project Activities
January 2001 - June 30, 2002

